REMARKS

Applicants respectfully request entry of the above amendments to the claims, and reconsideration of the application in light of the amendments to the claims and the arguments presented below. Applicants acknowledge with thanks withdrawal of previously-asserted grounds of rejection based on 35 U.S.C. §§101, 112, second paragraph, and 102(b) based on the McCoon reference.

The pending claims are set forth above. Claims 38 and 40-44, as herein amended, claims 45, 46 and 48, as filed are pending in this application. Claims 1-37, 39, 47 and 49-68 have been cancelled without prejudice or disclaimer. Support for the amendments presented herein can be found, *inter alia*, in the specification on p. 30, paragraph 1 and in Tables 1 and 2.

The amendments to the pending claims are made without prejudice or disclaimer, do not constitute amendments to overcome any prior art rejections under U.S.C. §§ 102 or 103, and are fully supported by the specification as filed. No new matter has been added as a result of the above amendments. The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below.

Claims rejections under 35 USC § 112, first paragraph (written description)

The Office maintains the previously-asserted rejection of claims 38, 41, 43-46 and 48 under 35 USC § 112, first paragraph, for not providing a written description of the invention so as to reasonably convey to one of skill in the art that the inventor(s), at the time the application was filed, had possession of the invention. The Action asserts that Applicants' earlier-presented argument has been considered but was not persuasive, because the Office did not consider the claims to recite characteristics of a common function.

Applicants disagree with the assertion made in the Action that the specification fails to teach structure or relevant identifying characteristics of a representative number of fragments of SEQ ID NO: 243. However, to expedite prosecution of the pending claims to allowance, Applicants have amended the claims to recite specifically-disclosed antigenic peptide fragments identified with reference to specific amino acids of an explicitly-disclosed polypeptide identified by SEQ ID NO: 243. Applicants have also amended their claim to recite that each of these explicitly-recited fragments comprises an antigenic epitope that is capable of causing an immunological response in a human. These amendments are fully supported by the specification as filed. For example, the specification discloses numerous fragments of SEQ ID NO: 243 (*inter alia*, on p. 12; Table 1 (on p. 73) and Table 2 (on p. 80)). The specification

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further provides a definition of term "fragments" (p. 23, paragraphs 2 and 3; p. 24, paragraphs 5, 6 & 7), and provides methods to make (*e.g.*, p. 31, paragraph 6) and select appropriate (antigenic) fragments (*e.g.*, p. 24, paragraphs 5, 6, 7), as well as methods to identify relevant amino acids (*e.g.*, p. 33). In addition, the specification discloses possible substitutions that can be made within SEQ ID NO: 243 to maintain its antigenicity (*e.g.*, p. 20, paragraph 6 and p. 23, last paragraph), predicted immunogenic amino acids (p. 30, paragraph 1 and 2; Table 1 on page p. 73) and serum reactive epitopes (Table 2, p. 80). Accordingly, Applicants respectfully contend that their specification discloses structural and functional features common to members of the species and features that constitute a sufficiently substantial portion of the genus. Moreover, the skilled worker would have appreciated that Applicants had possession of the invention as instantly claimed, and possession is the hallmark of the written description requirement. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555; 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991).

In light of Applicants explicit disclosure in their specification, and the amendments submitted herewith, Applicants believe that the rejection under 35 USC § 112, first paragraph has been overcome. They therefore respectfully request the Patent Office to reconsider and withdraw these grounds of rejection.

Claims rejections under 35 USC § 112, first paragraph (enablement)

The Office further maintains the previously-asserted rejection of claims 38, 40, 41, 43-46 and 48 under 35 USC §112, first paragraph, for failing to provide an enabling disclosure. The Action states that the specification fails to disclose all *S. pneumoniae* antigenic fragments that would be included due to the use of open claim language for fragments of SEQ ID NO: 243. More specifically, the Action asserts that using such open claim language would encompass any unknown fragment without any structure or other identifying characteristic. Moreover, the Action asserts that the specification does not disclose how to make such fragments retaining the antigenicity of the full length protein.

While not acquiescing to these grounds of rejection or the rationale supporting it, in order to further prosecution of the pending claims to allowance, Applicants have amended the claims to recite specifically-disclosed antigenic peptide fragments identified with reference to specific amino acids of an explicitly-disclosed polypeptide identified by SEQ ID NO: 243. In light of these amendments, Applicants respectfully contend that the claims reciting fragments of SEQ ID NO: 243 are fully enabled by their specification.

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Applicants note that in the previous Official Action, which the instant Action states recites the bases for the outstanding enablement rejection, affirmatively stated (on page 8 therein) that Applicants' specification was enabling for isolated *S. pneumoniae* antigens comprising SEQ ID NO: 243 and its recited antigenic fragments (while asserting additional purported deficiencies). Applicants respectfully contend that these deficiencies do not apply with regard to enablement of the antigenic peptide fragments explicitly recited in the pending claims as amended. These fragments are affirmatively characterized as being immunologically reactive in a human and capable of generating an immunological response in the human. Indeed, this capacity is evident from the description of how the fragments were identified, *viz.*, using sera from humans infected with *S. pneumoniae* in ELISA assays.

Applicants respectfully submit that the specification provides clear guidance to one of skill in the art for making the explicitly-recited antigenic peptide fragments of the polypeptide of SEQ ID NO: 243 and demonstrates immune response thereto. For example, the specification in Example 3 (and corresponding results shown in Table 1 on p. 73) shows regions of the polypeptide that are identified as immunogenic. In Example 4 (and corresponding results shown in Table 2 on p. 80) the specification discloses specific serum reactive epitopes. In addition, Example 7 (on p. 58) shows that the highest degree of protection was achieved by antigens representing SEQ ID NO: 243 (SP2216) along with other antigens. More specifically, Fig. 10 shows protection by the full length polypeptide of SEQ ID NO: 243 and fragments thereof. Thus, Applicants respectfully contend that the evidence contained in the specification as filed establishes that the explicitly-recited antigenic peptide fragments of the invention are capable of generating an immune response using an art-recognized animal model for immunogenicity. The specification further teaches one of ordinary skill in the art how to use the explicitly-recited antigenic peptide fragments of the polypeptide of SEQ ID NO: 243 to generate an immune response in an animal, as well as substitutions that can be made with SEQ ID NO: 243 to maintain its antigenicity (e.g., p. 20, paragraph 6 and p. 23, last paragraph). Furthermore, the specification at Example 4, Table 2 (p. 80) shows that antigenic fragments of SEQ ID NO: 243 could be detected by using human antisera, indicating that humans are capable of generating and in fact do generate an immune response to the polypeptide and antigenic fragments of SEQ ID NO: 243. The specification also discloses the use of the polypeptide of SEQ ID NO: 243 or its antigenic fragments in a pharmaceutical composition as vaccine.

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Based on this disclosure, Applicants respectfully submit that the specification provides enablement for their invention as instantly claimed throughout their entire scope, and that one of skill in art would not exercise undue experimentation to make or use the claimed invention. Accordingly, Applicants respectfully request that the Examiner withdraw this ground of rejection.

Claims rejections under 35 USC § 102

Claims 38, 40, 41, 42 (cancelled herein), 43-45 and 48 stand rejected under 35 USC §102(b) as being anticipated by Masignani et al. (WO 02/077021). The Office asserts that the Masignani reference discloses an isolated *S. pneumoniae* antigen with SEQ ID NO: 4652 that is 100% identical to the claimed SEQ ID NO: 243, along with pharmaceutical compositions comprising therapeutic amount of peptide SEQ ID NO: 4652.

Applicants respectfully disagree and submit that the Masignani reference merely discloses the amino acid sequence of an open reading frame of *S. pneumoniae* genomic DNA without disclosing whether in fact this polypeptide is actually produced by the bacteria. Moreover, the reference fails to disclose that the putative polypeptide is antigenic. Further, the Masignani reference fails to provide any teaching with regard to antigenic peptide fragments, particularly fragments that could produce protective immunogenic response. In particular, the Masignani reference does not identify any antigenic fragments whatsoever, and specifically does not identify the fragments identified by Applicants that are reactive with hyperimmune sera.

In response, the Action asserted that the antigenicity of the polypeptide was not recited as an affirmative limitation in the claims. Applicants have amended the pending claims to recite that the polypeptide identified as SEQ ID NO: 243 comprises an epitope capable of eliciting an immunological reaction in a human. Moreover, this limitation is shared by each of the explicitly-recited antigenic peptide fragments in the pending claims; the evidence of record establishes that the cited Masignani reference did not contain any disclosure relating to any of these particular antigenic fragments.

Thus, the Masignani reference does not disclose each and every limitation of Applicants' claims as required under 35 U.S.C. §102(b). Applicants respectfully submit that the Masignani reference does not anticipate their amended claims, and respectfully request that the Office withdraw this ground of rejection.

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CONCLUSION

Applicants respectfully contend that the instant application is in condition for allowance in view of the claim amendments and arguments presented above, and respectfully requests it be allowed.

If the Examiner believes that a telephone or personal interview would expedite prosecution of the instant application, the Examiner is respectfully invited to call the undersigned attorney at (312) 913-0001.

Respectfully submitted,
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